

harmony™
PRENATAL TEST



Clear **ANSWERS**
to Questions that Matter

Harmony Prenatal Test evaluates the risk for trisomies 21, 18, and 13 with unsurpassed accuracy in women of any age or risk category

A Higher Standard of Care in TRISOMY TESTING

AS EARLY AS 10 WEEKS, the Harmony Prenatal Test assesses the risk of trisomy 21 with unsurpassed accuracy in pregnant women, of any age or risk. In the first and only prospective blinded study of its kind published in the *New England Journal of Medicine*, the Harmony Prenatal Test proved superior to traditional first trimester combined screening for both detection rate and false-positive rate.¹⁵



Harmony is Validated in Women of All Ages ^{2-8, 11-13, 15}

- Harmony Prenatal Test is clinically validated for use in pregnant women, of any age or risk category, to assess the likelihood of fetal trisomies 21, 18 and 13
- Harmony is the most broadly studied cell-free DNA-based maternal blood test
 - Blinded clinical studies in >22,000 women of all ages
 - Over 400,000 pregnancies tested worldwide

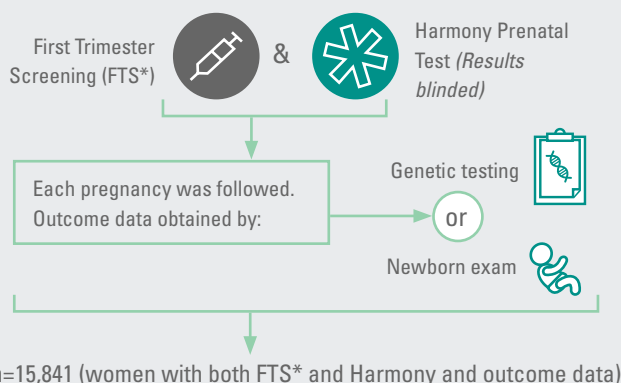
Harmony Outperforms First Trimester Combined Screening (FTS*) in both Detection and False-Positive Rate in a head to head comparison blinded study (n=15,841)

Study Population

Women (age 18-48, mean age of 30.7) with singleton pregnancies between 10 to 14 weeks gestation.

Study Design

18,955 enrolled & each woman received both



Study Results

n=15,841

Detection Rate

(more than 1 in 5 affected pregnancies may go undetected with FTS*)

p=0.008

Harmony	(38 of 38)	100%
FTS*	(30 of 38)	79%

False-Positive Rate

(Harmony reduces false-positives by more than 90-fold)

p<0.001

Harmony (9 of 15,803)	0.06%
FTS* (854 of 15,803)	5.4%

Positive Predictive Value (PPV)

(likelihood that a positive result is confirmed on diagnostic testing, based on false-positive rate and population frequency)

p<0.001

Harmony Prenatal Test	81%
FTS*	3.4%

*Serum PAPP-A, total or free β-hCG & Nuchal Translucency

Unsurpassed ACCURACY

Harmony Prenatal Test delivers unsurpassed accuracy when compared to any other trisomy 21 blood test.

In blinded studies of over 22,000 pregnant women age 18 to 50 for trisomy 21:

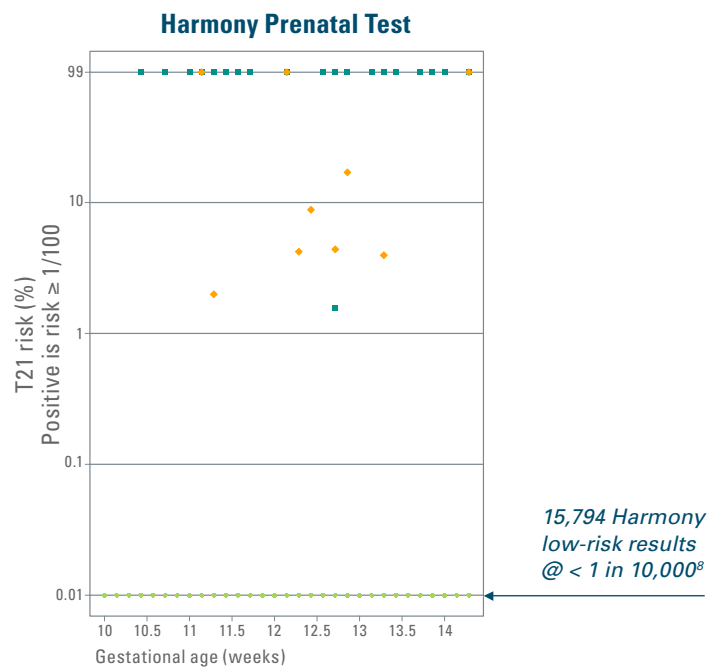
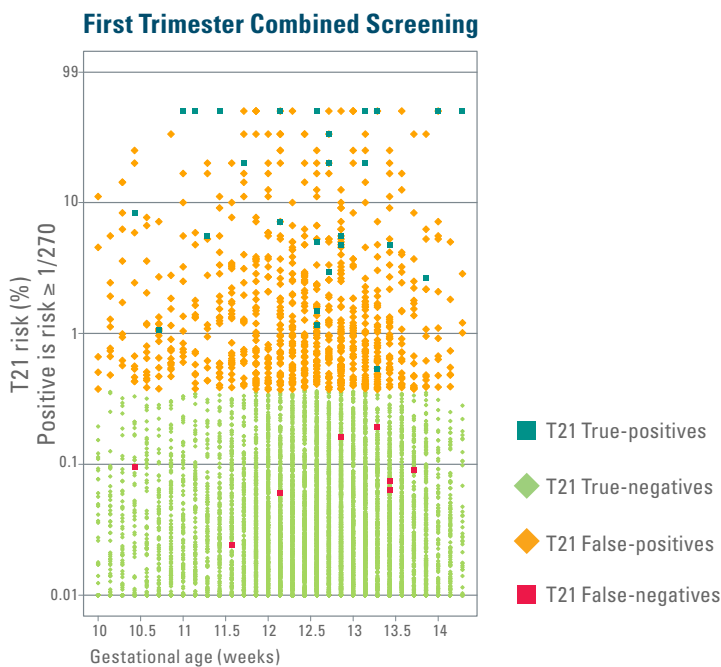
Harmony Performance Across All Blinded Studies ^{2-7,15}

Trisomy 21 PERFORMANCE		COMBINED PERFORMANCE (Trisomies 21, 18, 13) ¹⁴	
DETECTION RATE	>99%	DETECTION RATE	99%
FALSE-POSITIVE RATE	<0.1%	FALSE-POSITIVE RATE	<0.1%

The Difference in Performance is Clear

This study of blinded prospective 15,841 patients compares First Trimester Combined Screening (FTS*) with Harmony in a general pregnancy population.¹⁵

- The Harmony test accurately identified all 38 trisomy 21 cases, versus 30 out of 38 with FTS*.
- FTS* produced 5.4% (n=854) false-positives, compared to Harmony which had 0.06% (n=9) false-positives for trisomy 21



Exceptional Positive Predictive Value for the General Population

- 3.4% for first trimester screening versus 81% for Harmony (PPV is the likelihood that a positive result is confirmed on diagnostic testing, based on false-positive rate and population frequency)

Harmony's Targeted Technology Yields Optimal Results

- Only Harmony uses a unique targeted approach to more accurately assess the chromosomes of interest.
- Harmony's methodology includes precise measurement of the amount of fetal DNA and incorporates it into the risk assessment, providing a more accurate result.

Clear Answers Early to Reduce Follow-up

The greater accuracy and low false-positive rate of Harmony compared to traditional tests may minimize the chance further testing would be recommended due to a false-positive result.

Optional Fetal Sex Chromosome Assessment

- Information on sex chromosome aneuploidies can be requested.
 - Including risk for monosomy X, XXX, XXY, XYY, and XXYY.

⁸*Serum PAPP-A, total or free β-hCG & Nuchal Translucency

Why Choose Harmony?

- Unsurpassed accuracy for any age or risk
 - Blinded studies in over 22,000 women of all ages
 - Less than 0.1% false-positive rate for trisomy 21
- Most widely used test—in over 400,000 pregnancies and over 100 countries
- Performed as early as 10 weeks
- May minimize invasive procedures caused by false-positive results

Three Steps to Clarity



1. Draw a maternal blood sample at 10 weeks or later in pregnancy.



2. Submit sample directly to Ariosa Diagnostics or through one of our clinical laboratory partners.



3. Receive results in about 7 business days or less.

Visit us at harmonytest.com

For assistance email clientservices@ariosadx.com or call **1-855-9-ARIOSA (855-927-4672)**

Outside the USA, call **+1 925-854-6246**

Non-invasive prenatal testing based on cell-free DNA analysis is not considered diagnostic.